ISO 9000 AND THE OE TEAM

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Smart Business Practices

Abstract

In early 1996 the OE Directorate began researching ISO (International Organization for Standardization) 9000 series standards for application to the Directorate's internal processes. The decision was made to define our internal processes and document them in written procedures that could meet the intent of the International Standard.

This paper will describe the OE Quality Operating System (OEQOS); development of our procedures, the documentation system, problems encountered, benefits, and the future.

Background

The designation in April 1990 of Huntsville Center (Formerly Huntsville Division) as the U.S. Army Corps of Engineers (USACE) Mandatory Center of Expertise included the responsibility to develop an overall framework for response for the OE program. This included the development of policies and procedures that previously did not exist. There was also no documented guidance on how to execute OE projects.

Draft policies, Standing Operating Procedures (SOP), and other guidance documents were written to cover all aspects of the program from writing scopes of work to conducting field safety and quality oversight to writing final reports.

The only element missing was guidelines and procedures on how to conduct daily operations within the OE Team and to identify the processes that were essential to our quality system. For guidelines and a road map, we turned to the ISO 9000 series standards on Quality Systems.

Commitment

The first step in implementing ISO 9000 is to gain management commitment. The implementation of ISO 9000 standards requires resource commitment of time and funding. In June 1996, the OE Team contracted with 4D Incorporated from Huntsville, AL to provide training on how to implement ISO 9000. This training provided for a common understanding of the standard among various Divisions within Huntsville Center

from which further discussions and decisions would be based. By December 1996, the Director of the OE Team approved a Scope of Work for an ISO 9000 consultant to conduct a gap analysis and to assist in documenting our internal processes. This contract was also awarded to 4D Incorporated on 2 January 1997.

Development

The first step was to determine exactly which ISO 9000 series standard best fit our business. It was determined that the best standard for the OE Team was ISO 9001, *Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*. (ISO 9002 is for production, installation and servicing type activities and ISO 9003 is for final inspection and testing.)

We provided 4D, Inc. numerous documents, including the OE Field Operations Handbook, Project Management Manual, Draft Engineering Regulations and Pamphlets, and local SOPs. Based on the review of these documents and interviews with OE Team personnel, 4D, Inc. drafted a report describing how the current documentation and procedures compared with the requirements of an ISO 9001 quality system.

The ISO 9001 standard defines 21 essential elements of a quality system that should be addressed. Some of these elements are document control, contract review, design control, control of customer supplied product, process control, inspection and testing, and training. The entire OE Response process was reviewed and compared to the 21 elements to determine gaps between our daily activities and the standard. The gap analysis concluded that all elements were covered in varying degrees.

Our next step was to conduct an in-depth analysis of our entire process, compare it to each element, and pull it all together into an organized and documented system.

- For example, element 4 (paragraph 4.4 of the standard) covers *Design Control.* This element states that we shall establish and maintain documented procedures to control and verify the design of our product, including development planning, organizational interfaces, design input, output, review and verification. This is easy to understand in a manufacturing environment where a widget is designed and produced, but more difficult in a service type, knowledge based environment such as ours. However, the basic principle is the same. Each requirement listed under *Design Control* was interpreted to fit our daily activities. To meet the intent of the standard, we defined "design" as "those activities required to create and develop SOWs for Engineering Evaluations/Cost Analysis (EE/CA) and Removal Actions, and the subsequent management/oversight of contract performance." This process was repeated for every activity performed and every element of the standard.

After defining where each process fit into the standard a written procedure was developed. The traditional documentation system under ISO 9001 is multi-tiered and has three or four levels. Ours has four:

Level 1: Ordnance and Explosives Quality Manual (OEQM) – This document defines management responsibility, the quality policy, operating principles and defines the documentation system.

Level 2: Ordnance and Explosives Quality Procedures (OEQP) – These define the who, what, where and when of each process.

Level 3: ERs, ETLs, EPs, SOPs, Memoranda and Ordnance and Explosives Work Instructions (OEI), etc. – These are the how to documents.

Level 4: Records and objective evidence – These are the documents that provide evidence that procedures have been followed and are effective.

The OE Directorate's Quality Manual was written and approved in January 1997. The OEQM was used as the basis for developing twenty-eight (28) OEQPs and twenty-five (25) OEIs. These procedures were completed in September 1997.

Time Frames for Development of Selected OEQPs

OEQP #	Initial Mtg	POC Mtg	Draft Date	Draft Review	Cmts to 4D	Final Date	Copies to Gov.	Prep Time
01-01	6/12/97	6/12/97	6/12/97	6/12/97	8/5/97	8/5/97	8/8/97	2 Months
05-01	3/20/97	3/25/97	3/31/97	3/31/97	6/5/97	7/2/97	7/24/97	4 Months
09-02	4/18/97	5/7/97	5/7/97	5/7/97	8/5/97	9/3/97	9/3/97	4 Months
09-09	4/17/97	5/15/97	5/27/97	5/27/97	8/5/97	9/3/97	9/3/97	4 Months
11-01	7/7/97	7/7/97	8/4/97	8/4/97	8/14/97	8/14/97	8/14/97	1 Month
13-01	4/3/97	4/4/97	4/17/97	4/17/97	5/8/97	5/27/97	6/5/97	2 Months
14-02	2/20/97	3/31/97	3/31/97	4/4/97	6/30/97	6/30/97	6/30/97	4 Months
17-01	3/26/97	3/26/97	4/17/97	4/17/97	5/8/97	5/27/97	6/5/97	2 Months

- This table provides a brief understanding of the time frames involved in developing each OEQP. Time frames varied depending on complexity of the subject matter, availability of existing guidance, availability of subject matter experts, reviews by management, and ISO 9001 requirements. This process was used to develop 28 OEQPs, a Quality Manual, and various OEIs.

Implementation

Complete implementation has been difficult at times. Normal human resistance to change and heavy workload has contributed to our inability to completely implement our quality system. This does not mean we do not provide a quality service. The quality system however can provide a systematic means to improvement if completely implemented.

Implementation efforts have also been hindered by instability in key leadership positions within the OE Team. However, all leadership positions have recently been filled on a permanent basis. A new effort at complete implementation has begun.

Tools

A documented quality system provides a number of benefits to management; it provides consistency and control over daily activities, it can be used as a training aid for new employees, and it provides for feedback through the internal audit process.

The most powerful tool available to OE Team management is the corrective action process. This is a process by which OE Team members can document procedural and process deficiencies for management action. When a request for corrective action is written, the appropriate OE Team Manager must document the actual cause of the problem, the immediate solution, the long-term solution, and how he/she will follow up and monitor the effectiveness of the solution.

After a pre-determined time has elapsed, the Quality Assurance and Safety Team in the MCX conducts a follow-up review to assure management has implemented the corrective action. Most corrective action requests (CARs) written to date have resulted from project audits conducted at various sites. We have identified the need for additional procedures on SOW development, work plan review, and record keeping.

Each procedure is to be audited annually. The audit is to verify compliance by OE Team members, identify areas for improvement, and determine effectiveness of approved procedures.

Future

With stability in our key leadership positions, I anticipate a renewed effort to implement our quality system. Quality takes time, money and commitment, and we have made a tremendous start.